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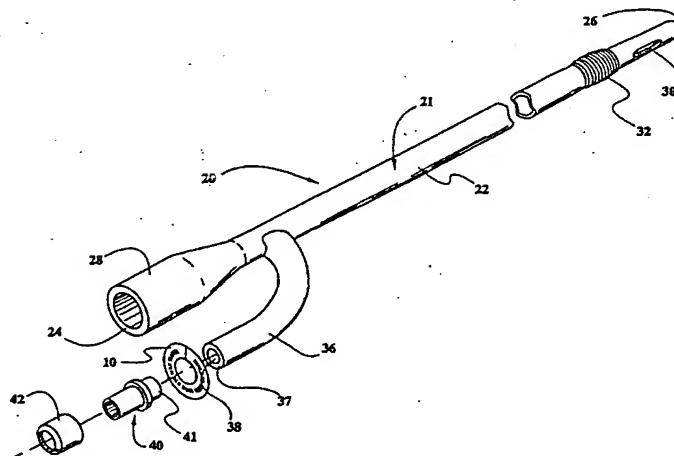
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(54) Title: TEAR-AWAY INFORMATION LABEL FOR MEDICAL DEVICES



(57) Abstract

A medical device is disclosed which has a tubular shaft and an information-bearing label disposed on the shaft. In a first embodiment the shaft has enlargements at both ends, and the label has an inner circumference which is larger than the circumference of the shaft but smaller than the circumference of the enlargements. In a second embodiment the label has radial slits extending outward from the central opening a predefined distance and dividing the inner portion of the label into a plurality of discrete tabs. The inner circumference of the label is smaller than the circumference of the shaft of the medical device, and the circumference defined by the outer ends of the radial slits is greater than the circumference of the shaft. When the label is placed over the free end of the shaft of a medical device, the tabs deform outward and exert a radially inward force on the periphery of the shaft which retains the label on the shaft. In the disclosed embodiments a perforation line is formed on the label to facilitate tearing the label off of the medical device in the event of a medical emergency.

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TEAR-AWAY INFORMATION LABEL FOR MEDICAL DEVICES

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TECHNICAL FIELD

The present invention relates generally to medical devices, and relates more specifically to a novel arrangement for affixing an information label to a medical device.

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BACKGROUND OF THE INVENTION

While medical devices such as catheters, drains, stents, and the like are well known and in widespread use, there is nonetheless a need to provide new or instructional information to teach a new user or to remind an experienced user of the proper use of the device. Preferably such instructional information should be affixed to the device, to eliminate the possibility that the information will inadvertently become separated from the device.

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There are difficulties inherent in providing such information directly on the device. First, curved or irregular surfaces of a medical device are not conducive to imprinting instructional material thereon. Adhesive labels suffer the disadvantage that if the label has to be removed from the device, an adhesive residue will likely remain. Further, an adhesive label can be difficult to remove in an emergency

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situation. Finally, many labeling solutions interfere with the assembly, sterilization, or packaging processes involved in manufacturing the medical device, or may be damaged by one or more of these processes.

An ideal label will thus satisfy the following criteria: (1) the label must be of sufficient size to hold the necessary information; (2) the label must be positioned on the device such that the information on the label is readily visible to the healthcare personnel using the device; (3) the label must be affixed in such a way that it will not inadvertently become separated from the device; (4) the label must be able to be removed quickly and easily in the event of an emergency; (5) once removed, the label must not leave an adhesive residue or other nonsterile remnant; and (6) the label must be easy to apply without interfering with, or being damaged by, the assembly, sterilization, and packaging processes involved in manufacturing the device. In addition, it would be advantageous if the label were inexpensive to manufacture and easy to apply to the device.

Thus there is a need for a means for providing information in conjunction with a medical device which meets the foregoing objectives.

SUMMARY OF THE INVENTION

Stated generally, the present invention comprises a label for providing information in conjunction with a medical device, such as a catheter, drain, stent, or the like. The label provides a sufficiently large, flat surface to hold instructional information and is positioned on the medical device such that the information on the label is readily visible to the healthcare personnel using the device. The label can be removed quickly and easily in the event of an emergency, and once removed, will not leave an adhesive residue or other nonsterile evidence of its presence. Further, the label is easy to apply to a medical device and does not interfere with, or

become damaged by, the assembly, sterilization, and packaging processes involved in manufacturing the device. Finally, the label is inexpensive to manufacture and easy to apply to the device.

5 Stated somewhat more specifically, in a first aspect the present invention relates to a label for a medical device comprising a tubular shaft with obstructions at both ends of the shaft. An information-bearing label is disposed on the tubular shaft, the shaft extending through the central opening of the label. The central opening of the label has a diameter which is less than the outer diameter of the obstruction, so that the label is prevented from sliding off the shaft by the obstruction. In one disclosed embodiment the tubular shaft comprises an inflation lumen of a catheter, and a cap fits onto the free end of the inflation lumen to retain a valve in place on the end of the inflation lumen. Also in the disclosed embodiment, the label is provided with a perforation line to facilitate tearing the label away from the catheter in the event of a medical emergency.

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20 In a second aspect the invention relates to a label
for a medical device comprising a tubular shaft with no
obstructions to prevent a label from sliding off a free end of
the shaft. An information-bearing label is disposed on the
tubular shaft, the shaft extending through the central opening
25 of the label. The label has a plurality of radial slits extending
from its inner circumference, dividing the portion of the label
immediately adjacent the central opening into a number of
discrete tabs. The inner circumference of the label is smaller
30 than the circumference of the shaft upon which it is to be
applied, and the circumference of the circle along which the
radial slits terminate is greater than the circumference of the
shaft. When the label is advanced over the free end of the
shaft, the tabs are deformed outward. The resiliency of the
35 tabs exerts a radially inward force around the circumference
of the shaft to retain the label on the shaft. Also in the second

disclosed embodiment, the label is provided with a perforation line to facilitate tearing the label away from the catheter in the event of a medical emergency.

Thus it is an object of the present invention to provide an improved medical device.

It is another object of the present invention to provide an improved arrangement for conveying information to a healthcare provider of a medical device.

It is still another object of the present invention to provide an arrangement for conveying information to a healthcare provider of a medical device which cannot easily become separated from the device.

Yet another object of the present invention is to provide a label for conveying information to a healthcare provider of a medical device which is securely affixed to the device but can be removed quickly and easily in the event of an emergency.

Still another object of the present invention is to provide an arrangement for affixing an instructional label to a medical device which can be quickly and easily removed in the event of an emergency.

It is a further object of the present invention to provide a method for affixing an instructional label to a medical device which, once removed, will not leave an adhesive residue or other non-sterile remnant on the device.

Other objects, features, and advantages of the present invention will become apparent upon reading the following specification, when taken in conjunction with the drawings and the appended claims.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a front view of a first embodiment of a tear-away information label for use on a medical device according to the present invention.

FIG. 2 is an exploded isometric view of a catheter with the tear-away information label of **FIG. 1**.

FIG. 3 is a view of the catheter of **FIG. 2** showing the components assembled and the label affixed.

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FIG. 4 is a front view of a second embodiment of a tear-away information label for use on a medical device according to the present invention.

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FIG. 5 is a perspective view of a medical device with information label of **FIG. 4**.

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DETAILED DESCRIPTION OF THE DISCLOSED EMBODIMENT

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Referring now to the drawings, in which like numerals indicate like elements throughout the several views, **FIG. 1** shows a tear-away information label **10** according to a preferred embodiment of the invention. The label **10** of the disclosed embodiment is in the form of a ring and has an inner circumference **11** defining a central opening **12**. Indicia **14** are printed on both faces of the label **10**. In the disclosed embodiment the label **10** bears the indicia "INFLATE WITH 10CC STERILE WATER." A perforation line **16** extends radially across one side of the label **10**. In the disclosed embodiment, the label **10** is comprised of TyvekTM, a spun-bonded olefin produced by DuPont. Another suitable material is KimduraTM, a multi-ply biaxially oriented polypropylene film produced by Kimberly-Clark. Other suitable materials will readily be identified by those skilled in the art.

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FIGS. 2 and 3 show a urological catheter **20**. The catheter of the disclosed embodiment is comprised of silicone or latex, though other suitable materials can also be used and will be readily identified by those skilled in the art. The catheter **20** includes a catheter body **21** comprising a drainage lumen **22** having a proximal end **24** and a distal end **26**. The proximal end **24** of the catheter **20** flares to form a connector **28** by which the drainage lumen **22** can be coupled by way of an interference fit to a tubing (not shown) to place the catheter

in fluid communication with a suitable container, such as a urinary drainage bag.

The drainage lumen 22 is tapered adjacent its distal end 26, and the distal end is rounded to minimize trauma to the patient. Ports or eyes 30 are defined adjacent the distal end 26 of the drainage lumen 22 to place the drainage lumen in fluid communication with the environment surrounding the distal end of the catheter. A balloon 32 surrounds the drainage lumen 22 proximal to the ports 30.

An inflation lumen 36 branches from the drainage lumen 22 and has a free end 37. The inflation lumen 36 extends obliquely from the drainage lumen 22 and then angles toward the proximal end 24 of the drainage lumen until the inflation lumen extends substantially parallel to the drainage lumen. A passage 38 extends the length of the inflation lumen 36 and then continues along the drainage lumen 22 toward its distal end and terminates within the balloon 32. The inflation lumen is thus in fluid communication with the interior of the balloon 32.

A valve 40 is positioned within the free end 37 of the inflation lumen 36 and has a port in fluid communication with the passage 38. The valve 40 includes a nipple 41 which fits within the outer end of the passage 38 of the inflation lumen. The outer diameter of the nipple 41 is slightly larger than the inner diameter of the passage 38 in the inflation lumen 36. Thus when the nipple 41 of the valve 40 is advanced into the free end of the inflation lumen, the inflation lumen distends radially outward. A cap 42 fits over the valve 40 to secure the valve to the inflation lumen 36. The cap 42 has an inner diameter which fits snugly over the distended free end 37 of the inflation lumen 36 such that the free end of the inflation lumen is captured between the nipple 41 of the valve and the inner circumference of the cap 42. The cap 42 has an outer diameter which is larger than the outer diameter of the inflation lumen 36.

It will be appreciated that all of the features of the catheter 20 thus far described are conventional and are well known to those skilled in the art.

The label 10 is captured on the inflation lumen 36 with the inflation lumen being received through the central opening 12 of the label. The inner diameter 11 of the label 10 is slightly larger than the outer diameter of the inflation lumen 36 but is smaller than the outer diameter of the cap 42. Thus the label 10 is prevented by the cap 42 from sliding off the free end 37 of the inflation lumen 36.

The body 21 of the catheter 20 consists of the drainage lumen 22, the balloon 32, and the inflation lumen 36. The catheter body 21 is formed by a conventional method well known to those skilled in the art in which the catheter body is built up in layers on a mandrel by a sequence of steps which involves dipping the mandrel into liquid latex. Since this process is conventional and well-known, it will not be explained in detail. In addition, other methods of manufacturing the catheter body, such as molding, can be employed, as the precise method of manufacture is not a part of the present invention.

Once the body 21 has been formed, an information label 10 is placed over the inflation lumen 36. The valve 40 and cap 42 are then installed onto the free end of the inflation lumen 36 in a conventional manner, capturing the label on the inflation lumen.

When the catheter 20 is removed from its packaging for use, the user will see the information label 10 on the inflation lumen 36 adjacent the valve 40. Instructions for use of the product are thus securely associated with the catheter 20 and will not accidentally become separated. Further, because of its proximity to the inflation valve 40, the information on the label 10 is easily seen, and in fact is difficult to miss. If it is desired to remove the information label 10 for some reason, such as a medical emergency, the

user simply tears the label along the perforation line 16. Once removed, the information label 10 does not leave an adhesive residue on the catheter 20 or any other evidence of its presence.

5 In addition to, or in place of, printed text on the information label 10, the indicia 14 can comprise a color code to convey information to the user. For example, an orange label can be used to indicate a 16 Fr. catheter, while a light blue label indicates a 24 Fr. catheter.

10 The foregoing arrangement by which the information label 10 is captured on the medical device by enlargements or blockages at both ends of a tubular structure works well with catheters and other such devices that have a tubular section blocked off at both ends. However, there are many medical devices which have tubular shafts upon which it would be desirable to place an information label but which do not include enlargements for capturing the label on the shaft. FIG. 4 illustrates an alternate embodiment of an information label 50 which can be used in such applications and which relies on a friction fit to retain the label on the shaft of a medical device.

15 The label 50 is annular and has an outer circumference 51 and an inner circumference 52 defining a central opening 53. One or more radially extending perforation lines 54 are formed in the label to provide a line of weakness along which the label can be torn to remove it from the medical device. Information 55 is imprinted on the face of the label 50. Optionally, the label 50 can be color-coded to convey information instead of, or in conjunction with, printed indicia 55.

20 A plurality of radial slits 56 are formed in the label beginning at its inner circumference 52 and radiating outward a short distance. The slits terminate along a circle 57 concentric with the inner circumference 52. The slits divide the portion of the label 50 immediately adjacent the central

opening 53 into a number of discrete tabs 58. With respect to a shaft of a medical device upon which the label 50 is intended to be used, the diameter of the inner circumference 52 of the label is less than the diameter of the shaft of the device, which in turn is less than the diameter of the circle 57 along which the radial slits 56 terminate.

FIG. 5 shows the label 50 mounted to a shaft 60 of a medical device such as a stent, drain, or other structure which lacks blockages at both ends for capturing a label on the shaft. The label 50 is advanced over the free end 62 of the shaft 60 with the shaft being received through the central opening 53 of the label. Because the diameter of the shaft 60 is greater than the diameter of the inner circumference 52 of the label 50, positioning the label on the shaft causes the tabs 58 to deflect outward. The resiliency of the material from which the label 50 is constructed causes the tabs 58 to tend to return to their original orientation, thereby exerting a radially inward force around the periphery of the shaft 60. In addition, while the rearward angle of the tabs 58 will permit the label 50 to be advanced easily over the free end 62 of the shaft 60, the angle of the tabs will also resist movement of the label on the shaft in the opposite direction such that the label, once installed, will not easily slide off the free end of the shaft. Should it become necessary to remove the label 50 quickly, the user can simply tear the label along one of the radial lines of perforation 54 to remove it from the device.

Without limiting the invention to any particular medical device or category of medical devices, the tear-away information label described above is suitable for use on Foley catheters; urine collection products such as drainage bags, drainage tubing, and sample ports; suprapubic drains; percutaneous drains; stents; stylets; ureteral catheters; urethral catheters; bladder evacuators; syringes; disposable inflation devices; dilation catheters; filiforms, followers, and bougies; dilators and sounds; guide wires; stone extractors; endoscopic

instruments; ureteroscopic instruments; syringe assist irrigation systems for endoscopy procedures; surgical drain systems; infusion catheters; and vena cava filter catheters.

While the tear-away information labels 10, 50 of the disclosed embodiments are shown in the form of annular rings, it will be understood that the invention is not limited to a circular or ring-shaped label. Also as used herein, the term "circumference" shall be understood to refer to the external boundary of an object, regardless of its shape, and is not meant to imply a circular shape. The periphery and opening of the label can have any suitable shape. Further, while the labels 10, 50 are described as having "central" openings, the invention is not limited to an opening located in the "center" of the label but will be understood to include any opening which is substantially entirely bound by the label.

Finally, it will be understood that the preferred embodiment has been disclosed by way of example, and that other modifications may occur to those skilled in the art without departing from the scope and spirit of the appended claims.

CLAIMS

What is claimed is:

5 1. A medical device comprising:

a tubular shaft having an outer diameter; enlargements attached at both ends of said tubular shaft, said enlargements having an outer diameter greater than said outer diameter of said tubular shaft; and

10 a label disposed on said tubular shaft, said label defining an opening through which said tubing extends, and said opening of said label being sized and configured such that said enlargements cannot pass therethrough,

15 whereby said label is prevented from sliding off said free end of said tubing by said enlargement.

2. The medical device of Claim 1, wherein

20 said medical device comprises a catheter having a catheter shaft, wherein said tubular shaft comprises a tubing branching off from said catheter shaft, and wherein said enlargements attached at both ends of said tubular shaft comprise said catheter shaft joined to one end of said inflation lumen and a valve cap attached to a second end of said tubing.

25 3. The medical device of Claim 1, wherein

said catheter shaft has an inflatable balloon afixed thereto, and wherein said tubing comprises an inflation lumen for inflating said balloon.

30 4. The medical device of Claim 3, wherein

said catheter product further comprises a valve, and wherein said cap is operative to retain said valve in operative relation with said free end of said tubing.

5. The medical device of Claim 1, wherein said information-bearing label has indicia imprinted thereon.

5 6. The medical device of Claim 1, wherein said information-bearing label is color-coded.

10 7. The medical device of Claim 1, wherein said information-bearing label comprises a weakened portion to facilitate tearing said label away from said tubing.

8. The medical device of Claim 7, wherein said weakened portion comprises perforations.

15 9. A medical device comprising:
a tubular shaft having an outer circumference;

20 a label having an opening formed therethrough, said label having a plurality of slits extending outward from said opening so as to divide a portion of said label adjacent said opening into a plurality of discrete tabs;

25 said opening of said label being smaller than said outer circumference of said tubular shaft, and a circumference defined by said outer ends of said radial slits being larger than said outer circumference of said tubular shaft;

30 said label being disposed on said tubular shaft, said shaft extending through said opening and displacing at least some of said plurality of tabs outward, said tabs being resilient so as to exert a radially inward force on said tubular shaft to retain said label on said shaft.

10. The medical device of Claim 9, wherein said plurality of slits extend radially outward from said opening a predefined distance therefrom such that the outer ends of said slits define a circumference, said circumference defined by said outer ends of said slits being greater than said outer circumference of said shaft.

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11. The medical device of Claim 10, wherein said radial slits extend from said opening to a circle outward of and concentric with said central opening, and wherein said circle has a circumference which is larger than said circumference of said tubular shaft.

12. The medical device of Claim 9, wherein said information-bearing label has indicia imprinted thereon.

13. The medical device of Claim 9, wherein said information-bearing label is color-coded.

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14. The medical device of Claim 9, wherein said information-bearing label comprises a weakened portion to facilitate tearing said label away from said tubing.

15. The medical device of Claim 14, wherein said weakened portion comprises perforations.

AMENDED CLAIMS

[received by the International Bureau on 21 July 1998 (21.07.98);
original claims 1-4, 7, 9 and 15 amended;
remaining claims unchanged (3 pages)]

5 1. A medical device comprising:
a tubular shaft having an outer diameter;
enlargements attached at both ends of said
tubular shaft, said enlargements having an outer diameter
greater than said outer diameter of said tubular shaft; and
10 an information-bearing label disposed on
said tubular shaft, said label defining an opening through
whis. nd said opening of said label being sized and
configured such that said enlargements cannot pass
therethrough,

15 whereby said label is prevented from
sliding off said tubular shaft by said enlargements.

20 2. The medical device of Claim 1, wherein
said medical device comprises a catheter having a catheter
shaft, wherein said tubular shaft comprises a tubing branching
off from said catheter shaft, and wherein said enlargements
attached at both ends of said tubular shaft comprise said
catheter shaft joined to one end of said tubing and a valve cap
attached to a second end of said tubing.

25 3. The medical device of Claim 2, wherein
said catheter shaft has an inflatable balloon affixed thereto, and
wherein said tubing comprises an inflation lumen for inflating
said balloon.

30 4. The medical device of Claim 3, wherein
said catheter further comprises a valve, and wherein said valve
cap is operative to retain said valve in operative relation with
said second end of said tubing.

5. The medical device of Claim 1, wherein said information-bearing label has indicia imprinted thereon.

6. The medical device of Claim 1, wherein
said information-bearing label is color-coded.

10 an outer edge of said label to facilitate tearing said label away
from said tubing.

8. The medical device of Claim 7, wherein said weakened portion comprises perforations.

15 9. A medical device comprising:
a tubular shaft having an outer
circumference; and

an information-bearing label having an opening formed therethrough, said label having a plurality of slits extending outward from said opening so as to divide a portion of said label adjacent said opening into a plurality of discrete tabs;

25 circumference defined by said outer ends of said radial slits being larger than said outer circumference of said tubular shaft; and

30 said label being disposed on said tubular shaft, said shaft extending through said opening and displacing at least some of said plurality of tabs outward, said tabs being resilient so as to exert a radially inward force on said tubular shaft to retain said label on said tubular shaft.

5 **10.** The medical device of Claim 9, wherein
said plurality of slits extend radially outward from said
opening a predefined distance therefrom such that the outer
ends of said slits define a circumference, said circumference
defined by said outer ends of said slits being greater than said
outer circumference of said shaft.

10 **11.** The medical device of Claim 10, wherein
said radial slits extend from said opening to a circle outward
of and concentric with said central opening, and wherein said
circle has a circumference which is larger than said
circumference of said tubular shaft.

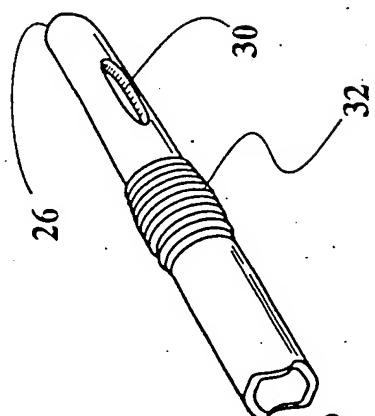
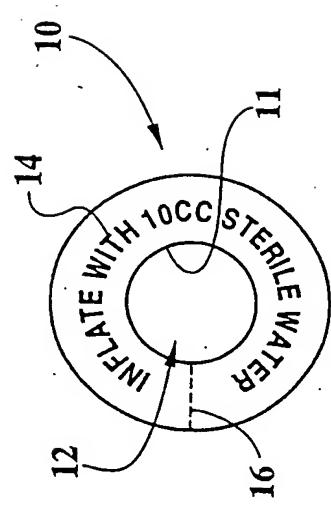
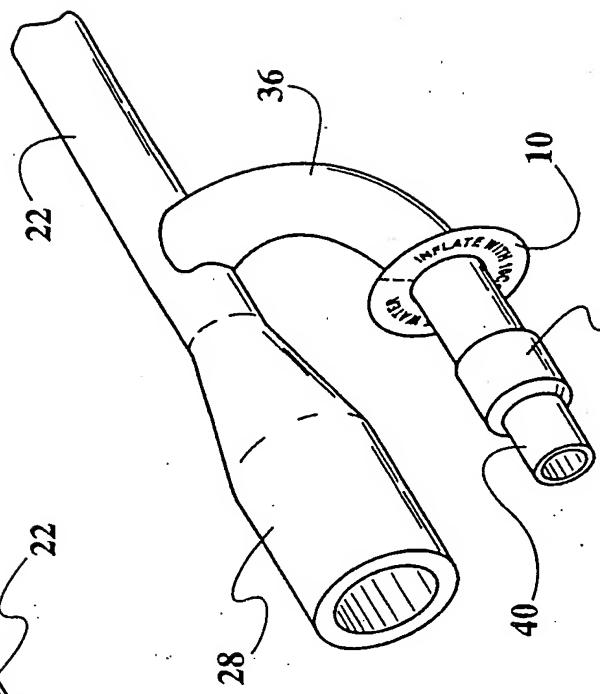
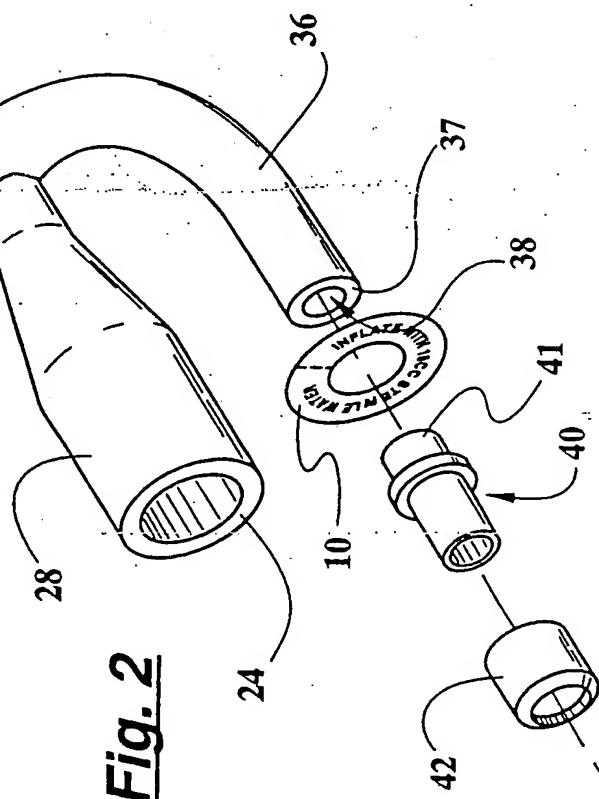
15 **12.** The medical device of Claim 9, wherein
said information-bearing label has indicia imprinted thereon.

13. The medical device of Claim 9, wherein
said information-bearing label is color-coded.

20 **14.** The medical device of Claim 9, wherein
said information-bearing label comprises a weakened portion
to facilitate tearing said label away from said tubing.

25 **15.** The medical device of Claim 9, wherein
said weakened portion comprises perforations.

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Fig. 1Fig. 2Fig. 3

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Fig. 5

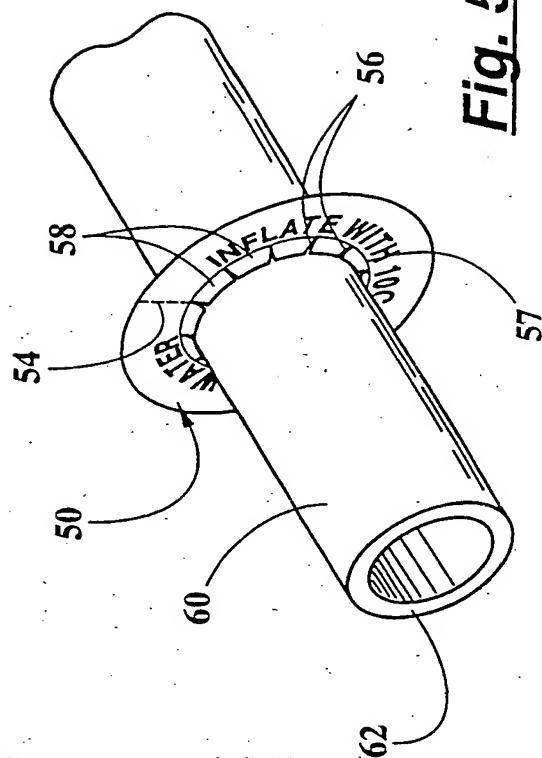
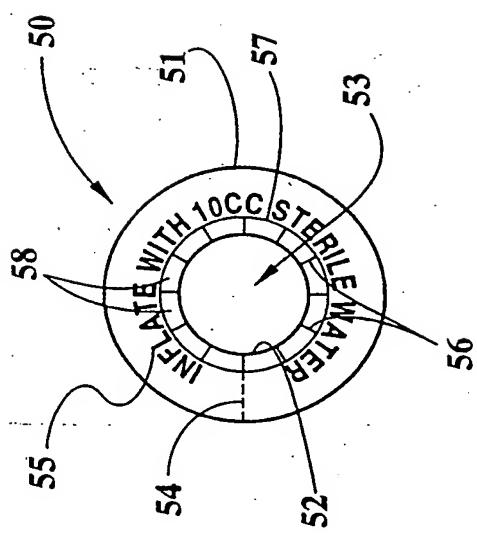


Fig. 4



INTERNATIONAL SEARCH REPORT

Int'l. Jonal Application No

PCT/US 98/01069

A. CLASSIFICATION OF SUBJECT MATTER
 IPC 6 A61M25/00 A61B19/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 6 A61M A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim-No.
A	US 5 489 275 A (THOMPSON ET AL.) 6 February 1996 see abstract see column 1, line 38 - column 2, line 13; figures 1,2,5,7,14	1-15
A	US 4 619 640 A (POTOLSKY ET AL.) 28 October 1986 see abstract see column 1, line 34 - line 45; figures 1-3	1-15
A	US 4 116 227 A (EISENBERG ET AL.) 26 September 1978 see abstract see column 2, line 12 - line 59; figure 1	1-15

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Patent family members are listed in annex.

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Date of the actual completion of the international search

Date of mailing of the international search report

19 May 1998

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INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 98/01069

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT		
Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5 531 723 A (SOLAZZO) 2 July 1996 see abstract see column 3, line 3 - line 20; figures 1,3 -----	1-15
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